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VASCULAR DISEASE

A PERCUTANEOUS DEVICE FOR CEREBRAL EMBOLIC PROTECTION DURING HIGH RISK CARDIOVASCULAR INTERVENTION

ACC Poster Contributions
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Background: Embolic stroke is a major cause of morbidity surrounding aortic and cardiac interventional procedures. While cerebral embolic protection devices have been developed for carotid interventions and for open heart surgery, a percutaneous device for cerebral embolic protection during aortic and cardiac interventions would be desirable.

Method: The Embrella Embolic DeflectorTM is a percutaneously placed embolic protection device, inserted via 6 French access in the right forelimb and deployed in the aorta, covering the brachiocephalic vessel origins. The device functions by deflecting embolic debris downstream in the aortic circulation. A swine model (n=3[jg1]) was developed for testing the deployment, retrieval and efficacy of the device employing a carotid filtration circuit for collection of emboli. Human atheromatous material was prepared as embolization particles between 150-600μ diameter. Deflection efficiency of the device was calculated by comparing numbers of embolic particles in the carotid circulation during protected and unprotected injections.

Results: The device was reliably deployed, positioned and retrieved (n=8). There was no significant drop in blood pressure across the membrane of the device to suggest reduction of cerebral blood flow. The device did not become occluded by embolic debris despite an embolic load many times that encountered in the clinical situation. Particles entering the carotid circulation after aortic injection of emboli were reduced from 20.8% (unprotected) to 3.3% (protected, $p < 0.0001$), with 96.7% of all injected particles being deflected downstream. There was no evidence of arterial injury related to the device found at autopsy.

Conclusion: The Embrella Embolic DeflectorTM performs safely and reliably in the swine model of human atheroembolism. It effectively deflects the vast majority of emboli downstream, away from the carotid circulation. The deflector shows promise as an aortic embolic protection device and merits further investigation.